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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,417	11/19/2003	Eivind Per Thor Straten	60820.000004	5850

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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,417	STRATEN ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003 and 21 April 2004*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments filed 11/19/03 and 4/21/04 are acknowledged and have been entered.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-40, drawn to an MHC class I-restricted epitope peptide derived from servivin, composition thereof and kit comprising said peptide, and complex of peptide and HLA class I or fragment thereof, classified in Class 530, subclass 328, Class 424, subclass 185.1 and Class 435, subclass 810, and Class 530, subclass 350, respectively.

II. Claim 41, drawn to a method of detecting in a cancer patient the presence of survivin reactive T cells, said method comprising contacting a tumor tissue or blood sample with a complex, classified in Class 435, subclass 7.1.

III. Claims 42 and 43, drawn to a molecule capable of specifically binding a peptide, classified in Class 530, subclass 387.1.

IV. Claim 44, drawn to a molecule that is capable of blocking the binding of a molecule that is capable of specifically binding to a peptide, classified in Class 530, subclass 350.

V. Claims 45-49, drawn to a method of treating a cancer disease, said method comprising administering to a patient a composition comprising a peptide, classified in Class 424, subclass 185.1.

VI. Claims 45-49, drawn to a method of treating a cancer disease, said method comprising administering a molecule that binds specifically to a peptide, classified in Class 424, subclass 138.1.

VII. Claims 45-49, drawn to a method of treating a cancer disease, said method comprising administering a molecule capable of blocking the binding of a molecule that is capable of specifically binding to a peptide, classified in Class 424, subclass 131.1.

3. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or diagnostic assays.

5. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or *in vivo* methods of treatment.

6. Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

7. Inventions IV and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as an in isolation protocols or detection assays.

8. Inventions V, VI and VII are directed to related methods.

The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, *i.e.,* are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design in that they treat a cancer disease using either a peptide (V), a molecule capable of specifically binding a peptide (VI) or a molecule capable of blocking the binding of a molecule capable of specifically binding a peptide (VII). Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

9. (Invention II) and (Inventions V, VI and VII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions require different ingredients and process steps to accomplish the use of detecting cancer in a patient (Invention II) or treating a cancer disease (each of Inventions V-VII). For example, the method of invention II is an *in vitro* detection assay using a complex of peptide/HLA class I to detect survivin reactive T cells in a tumor tissue or blood sample, whereas the methods of inventions V-VII are *in vivo* methods of treating a cancer disease

10. Inventions are I, III and IV unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are a peptide epitope from survivin that elicits a CTL response (Invention I), or a molecule that is an antibody that specifically binds the survivin peptide epitope of survivin (Invention III) or is a molecule that is capable of blocking the binding of a molecule that is capable of specifically binding to a survivin peptide epitope such as for example, an anti-idiotypic antibody that binds the idiotype of antibody 1 or a peptidomimetic (Invention IV). These molecules have different structures and modes of action.

Therefore they are patentably distinct.

11. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-VII is not required for any other group from Groups I-VII and Groups I-VII have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

12. **If Applicant elects the invention of Group I**, Applicant is further required to (1) elect a single disclosed species of peptide, complex thereof, composition thereof, kit thereof (***a specific peptide that binds a specific class I MHC molecule***, for example, LLLGEFLKL (SEQ ID NO: 4) that binds to HLA-A2, composition and kit thereof, and monomeric complex of SEQ ID NO: 4/HLA-A2 to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

In addition, Applicant is further required to (1) elect a single disclosed species of second peptide to be used in combination with the first elected species of peptide in one of the compositions of claim 26 or 27 (***a specific peptide that binds a specific class I***, for example, CPTENEPDY (SEQ ID NO: 8) that binds to HLA-B35 which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

13. **If Applicant elects the invention of Group II**, Applicant is further required to (1) elect a single disclosed species of complex to be used in the claimed method (***a specific peptide that binds a specific class I MHC molecule***, for example, LLLGEFLKL (SEQ ID NO: 4) that binds to HLA-A2 to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

14. **If Applicant elects the invention of Group III**, Applicant is further required to (1) elect a single disclosed species of molecule that is capable of specifically binding a specific peptide (**an antibody that binds a *specific peptide that binds a specific class I MHC molecule***, for example, an antibody that binds LLLGEFLKL (SEQ ID NO: 4) that binds to HLA-A2 to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

15. **If Applicant elects the invention of Group IV**, Applicant is further required to (1) elect a single disclosed species of molecule that is capable of blocking the binding of a molecule that specifically binds a specific peptide (**an anti-idotypic antibody that binds an antibody that binds a *specific peptide that binds a specific class I MHC molecule***, for example, an antibody that binds LLLGEFLKL (SEQ ID NO: 4) that binds to HLA-A2 to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

16. **If Applicant elects the invention of Group V**, Applicant is further required to (1) elect a single disclosed species of peptide composition to be used in the claimed method and a specific disease to be treated (**a *specific peptide that binds a specific class I MHC molecule***, for example, LLLGEFLKL (SEQ ID NO: 4) that binds to HLA-A2 and treating melanoma, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

17. **If Applicant elects the invention of Group VI**, Applicant is further required to (1) elect a single disclosed species of molecule that is capable of specifically binding a specific peptide to be used in the claimed method and a specific disease to be treated (**an antibody that binds a *specific peptide that binds a specific class I MHC molecule***, for example, an antibody that binds LLLGEFLKL (SEQ ID NO: 4) that binds to HLA-A2 and treating melanoma, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

18. **If Applicant elects the invention of Group VII**, Applicant is further required to (1) elect a single disclosed species of molecule that is capable of blocking the binding of a molecule that specifically binds a specific peptide to be used in the claimed method and a specific disease to be treated (**an anti-idotypic antibody that binds an antibody that binds a *specific peptide that binds a specific class I MHC molecule***, for example, an antibody that binds LLLGEFLKL (SEQ ID NO: 4) that binds to HLA-A2 and treating melanoma, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

19. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

20. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

21. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

22. Should Applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

23. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

24. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

25. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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